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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,748	06/18/2001	Kunio Shiota	04853.0074	8762
22852	7590	11/21/2005	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			LIN, JERRY	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 11/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/881,748		SHIOTA ET AL.	
	Examiner		Art Unit	
	Jerry Lin		1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/15/05
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-9, 14 and 17-23 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-7, 9, 17, 18, 20, 22 and 23 is/are rejected.
- 7) ☒ Claim(s) 8, 19 and 21 is/are objected to.
- 8) ☒ Claim(s) 4-9, 14 and 17-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

con. AM
11-7-05

Applicants' arguments, filed July ¹⁵~~22~~, 2005 have been fully considered and they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claim 22, from lines 16 to the end of the claim, lists DNA methylation patterns that identify particular cell types. It is unclear if a match to a DNA methylation pattern would result in the identification of all of the different listed cell types or if only one listed cell type will be identified. For purposes of this examination, it will be assumed that only one listed cell type is identified with a match to a DNA methylation pattern.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-7, 9, 17, 18, 22, 20, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olek et al. (US 6,214,556 B1) in view of Ohgane et al. (Development Genetics Volume 22, pages 132-140).

Please see the previous office action for the teachings of Olek et al. and Ohgane et al.

The applicants have responded to this rejection by stating that combined disclosures do not teach or suggest "identifying the differentiation state of a test cell, tissue, or nucleus," "a differentiation state-specific DNA methylation pattern," or "comparing the DNA methylation pattern for the test cell, tissue or nucleus with a differentiation state-specific DNA methylation pattern for a cell, tissue, or nucleus of known differentiation state." The Examiner respectfully disagrees.

Olek et al. teaches a generic method of identifying cells types as well as cell states or stages though the use of methylation fingerprint patterns (column 14, lines 50-58; column 17, lines 30-40; column 2, lines 35-44; column 24-25). In his method he teaches obtaining a DNA methylation pattern for a test cell (columns 24-25); obtaining a reference pattern for a particular cell type (columns 24-25); comparing the test cell DNA methylation pattern with the reference pattern (columns 24-25); and matching the test cell DNA methylation pattern with a reference pattern to determine the cell type (columns 24-25).

However, Olek et al. do not specifically teach using a reference pattern for differentiation states to determine the differentiation state of a test cell. In other words, Olek et al. teach the generic version of the instant claims where a practitioner may use their method to determine any cell type or stage, but Olek et al. do not teach the instant claims as the are specifically applied to differentiation states.

Applicants have stated that Ohgane et al.'s recognition of the involvement of methylation in differentiation is not the equivalent of a "differentiation state-specific DNA methylation pattern." However, Ohgane et al. provide "differentiation state-specific DNA methylation patterns" that distinguished the placenta from kidney (page 134, right column, bottom paragraph – page 136). Specifically, Ohgane et al. compare the DNA methylation patterns and find that the spots in Group II are found in the placenta but not in the kidney. They also find that the spots in Group IV are found in the kidney but not in the placenta. Using the DNA methylation patterns of this description, a practitioner

may distinguish between tissue from the placenta and the kidney. Thus the DNA methylation patterns in Ohgane et al. are differentiation state-specific.

Given that Olek et al. provide a method of identifying cell types using DNA methylation patterns and Ohgane et al. provide DNA methylation patterns specific to differentiation states, the combination of the methods would create a method of identifying differentiation states using DNA methylation patterns specific to differentiation states. Thus the combination of the two teaches the limitation of instant claim 5.

Regarding claims 22, 20 and 23, Ohgane et al. teach obtaining DNA methylation patterns for the kidney or placenta (a differentiated cell) (page 134, right column, bottom paragraph – page 136) and generating DNA methylation patterns with RLGS profiles (Figure 1 and Tables 1-3).

One of ordinary skill in the art at the time the invention was made would have combined the methods of Olek et al. with Ohgane et al. to create a method of identifying kidney or placental tissue to identify unknown cell samples. Olek et al. teaches a generic method of identifying cell types through DNA methylation patterns. Ohgane et al. provides a DNA methylation pattern. Thus one of ordinary skill in the art would be motivated to take the DNA methylation pattern from Ohgane et al. and incorporate it into Olek et al.'s method in order to identify placental or kidney tissue.

This rejection is maintained from the previous Office Action and necessitated by amendment.

Allowable Subject Matter

Claims 8, 19 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 6:30-5:00, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system

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For all other customer support, please call the USPTO Call Center at (800) 786-9199.

Ardin H. Marschel 11/7/05
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER

JL